

Message

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**From:** Miller, Wynne [Miller.Wynne@epa.gov]  
**Sent:** 1/31/2019 10:52:25 PM  
**To:** McNally, Robert [McNally.Robert@epa.gov]  
**CC:** Keigwin, Richard [Keigwin.Richard@epa.gov]; Messina, Edward [Messina.Edward@epa.gov]  
**Subject:** Re: FROM OMB: EO 12866 Interagency Review: EPA's Guidance for Plant Biostimulant Products: Label Claims Excluded or Regulated under FIFRA as Plant Regulator Claims (RIN 2070-ZA21) - Interagency Comments

TJ asked to have until the end of this week on OMB's proposed revisions to the economic language but Melissa said he could have 2 weeks. I don't think that BEAD will need 2 weeks for our part. Not sure how today's USDA comments (and responses to those) impact the turnaround time.

Wynne

Sent from my iPhone

On Jan 31, 2019, at 5:41 PM, McNally, Robert <McNally.Robert@epa.gov> wrote:

BEAD status on the comments.

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**From:** Chun, Melissa  
**Sent:** Tuesday, January 29, 2019 3:38 PM  
**To:** Wyatt, TJ <Wyatt.TJ@epa.gov>; Jones, Russell <Jones.Russell@epa.gov>; McNally, Robert <McNally.Robert@epa.gov>; Hofmann, Angela <Hofmann.Angela@epa.gov>; Chumble, Prasad <Chumble.Prasad@epa.gov>; Smoot, Cameo <Smoot.Cameo@epa.gov>; Hoyt, Sarita <Hoyt.Sarita@epa.gov>; Mosby, Jackie <Mosby.Jackie@epa.gov>; Miller, Wynne <Miller.Wynne@epa.gov>  
**Cc:** Kiely, Timothy <Kiely.Timothy@epa.gov>  
**Subject:** RE: FROM OMB: EO 12866 Interagency Review: EPA's Guidance for Plant Biostimulant Products: Label Claims Excluded or Regulated under FIFRA as Plant Regulator Claims (RIN 2070-ZA21) - Interagency Comments

Hi TJ. How about 2 weeks? Let me know if you need more time.

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**From:** Wyatt, TJ  
**Sent:** Tuesday, January 29, 2019 3:34 PM  
**To:** Chun, Melissa <Chun.Melissa@epa.gov>; Jones, Russell <Jones.Russell@epa.gov>; McNally, Robert <McNally.Robert@epa.gov>; Hofmann, Angela <Hofmann.Angela@epa.gov>; Chumble, Prasad <Chumble.Prasad@epa.gov>; Smoot, Cameo <Smoot.Cameo@epa.gov>; Hoyt, Sarita <Hoyt.Sarita@epa.gov>; Mosby, Jackie <Mosby.Jackie@epa.gov>; Miller, Wynne <Miller.Wynne@epa.gov>  
**Cc:** Kiely, Timothy <Kiely.Timothy@epa.gov>  
**Subject:** RE: FROM OMB: EO 12866 Interagency Review: EPA's Guidance for Plant Biostimulant Products: Label Claims Excluded or Regulated under FIFRA as Plant Regulator Claims (RIN 2070-ZA21) - Interagency Comments

Hi, all! I'm going to have to dust off some brain cells. Can I have until the end of the week to get back to you?

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**From:** Chun, Melissa  
**Sent:** Tuesday, January 29, 2019 3:23 PM  
**To:** Jones, Russell <Jones.Russell@epa.gov>; McNally, Robert <McNally.Robert@epa.gov>; Varco, Joseph

<varco.joseph@epa.gov>; Gsell, Alyssa <Gsell.Alyssa@epa.gov>; Kaczmarek, Chris <Kaczmarek.Chris@epa.gov>; Ambrosino, Helene <Ambrosino.Helene@epa.gov>; VanAkkeren, Brett <VanAkkeren.Brett@epa.gov>; Wyatt, TJ <Wyatt.TJ@epa.gov>; Hofmann, Angela <Hofmann.Angela@epa.gov>; Chumble, Prasad <Chumble.Prasad@epa.gov>; Smoot, Cameo <Smoot.Cameo@epa.gov>; Watkins, Stephen <watkins.stephen@epa.gov>; Hoyt, Sarita <Hoyt.Sarita@epa.gov>; Mosby, Jackie <Mosby.Jackie@epa.gov>; Miller, Wynne <Miller.Wynne@epa.gov>

**Subject:** FW: FROM OMB: EO 12866 Interagency Review: EPA's Guidance for Plant Biostimulant Products: Label Claims Excluded or Regulated under FIFRA as Plant Regulator Claims (RIN 2070-ZA21) - Interagency Comments

Hi all,

Welcome back.

Here's where we left off on biostimulants:

## Ex. 5 Deliberative Process (DP)

Are folks o.k. with OMB's proposed revisions to D: What are the Potential Economic Impacts of Taking this Action? Comment [A2].

## Ex. 5 Deliberative Process (DP)

The Guidance document still needs work.

Please review and provide your comments on the FR document and guidance document.

We'll need to get our responses back to OMB.

I'll check with Danielle about USDA's comments and rescheduling the DOJ call.

Thanks!

-Melissa

**From:** Jones, Russell

**Sent:** Wednesday, December 19, 2018 7:32 AM

**To:** Chun, Melissa <Chun.Melissa@epa.gov>; McNally, Robert <McNally.Robert@epa.gov>; Varco, Joseph <varco.joseph@epa.gov>; Gsell, Alyssa <Gsell.Alyssa@epa.gov>; Kaczmarek, Chris <Kaczmarek.Chris@epa.gov>; Ambrosino, Helene <Ambrosino.Helene@epa.gov>; VanAkkeren, Brett <VanAkkeren.Brett@epa.gov>; Wyatt, TJ <Wyatt.TJ@epa.gov>; Hofmann, Angela <Hofmann.Angela@epa.gov>; Chumble, Prasad <Chumble.Prasad@epa.gov>; Smoot, Cameo <Smoot.Cameo@epa.gov>; Watkins, Stephen <watkins.stephen@epa.gov>; Hoyt, Sarita <Hoyt.Sarita@epa.gov>; Mosby, Jackie <Mosby.Jackie@epa.gov>; Miller, Wynne <Miller.Wynne@epa.gov>

**Subject:** RE: FROM OMB: EO 12866 Interagency Review: EPA's Guidance for Plant Biostimulant Products: Label Claims Excluded or Regulated under FIFRA as Plant Regulator Claims (RIN 2070-ZA21) - Interagency Comments

I am OK with the new language.

Russell S. Jones, Ph.D., Senior Scientist  
Chair, Biochemical Classification Committee  
Risk Assessment Branch  
Biopesticides & Pollution Prevention Division  
Office of Pesticide Programs  
US Environmental Protection Agency

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<http://www.epa.gov/pesticides>  
<image001.jpg> <image002.jpg>

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**From:** Chun, Melissa

**Sent:** Tuesday, December 18, 2018 5:39 PM

**To:** Jones, Russell <[Jones.Russell@epa.gov](mailto:Jones.Russell@epa.gov)>; McNally, Robert <[McNally.Robert@epa.gov](mailto:McNally.Robert@epa.gov)>; Varco, Joseph <[varco.joseph@epa.gov](mailto:varco.joseph@epa.gov)>; Gsell, Alyssa <[Gsell.Alyssa@epa.gov](mailto:Gsell.Alyssa@epa.gov)>; Kaczmarek, Chris <[Kaczmarek.Chris@epa.gov](mailto:Kaczmarek.Chris@epa.gov)>; Ambrosino, Helene <[Ambrosino.Helene@epa.gov](mailto:Ambrosino.Helene@epa.gov)>; VanAkkeren, Brett <[VanAkkeren.Brett@epa.gov](mailto:VanAkkeren.Brett@epa.gov)>; Wyatt, TJ <[Wyatt.TJ@epa.gov](mailto:Wyatt.TJ@epa.gov)>; Hofmann, Angela <[Hofmann.Angela@epa.gov](mailto:Hofmann.Angela@epa.gov)>; Chumble, Prasad <[Chumble.Prasad@epa.gov](mailto:Chumble.Prasad@epa.gov)>; Smoot, Cameo <[Smoot.Cameo@epa.gov](mailto:Smoot.Cameo@epa.gov)>; Watkins, Stephen <[watkins.stephen@epa.gov](mailto:watkins.stephen@epa.gov)>; Hoyt, Sarita <[Hoyt.Sarita@epa.gov](mailto:Hoyt.Sarita@epa.gov)>; Mosby, Jackie <[Mosby.Jackie@epa.gov](mailto:Mosby.Jackie@epa.gov)>; Miller, Wynne <[Miller.Wynne@epa.gov](mailto:Miller.Wynne@epa.gov)>

**Subject:** FW: FROM OMB: EO 12866 Interagency Review: EPA's Guidance for Plant Biostimulant Products: Label Claims Excluded or Regulated under FIFRA as Plant Regulator Claims (RIN 2070-ZA21) - Interagency Comments

Hi all,

I asked Danielle about Comment [A13], page 12, line 236 in the guidance document, which recommends soliciting comment on the different proposed definitions and if EPA should consider codifying a definition for PBS in a future rulemaking.

Alyssa had commented that it's unclear which proposed definitions (the farm bill or the EU definition) they are referring to. And it might be helpful to specify which proposed definitions. That clarification should also make it clear to the reader that EPA is not proposing a definition with this document.

## Ex. 5 Deliberative Process (DP)

I said that we were thinking about adding a sentence to the guidance document and the FR Notice along the lines of:

## Ex. 5 Deliberative Process (DP)

She is o.k. with the revised language.

-Melissa

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**From:** Chun, Melissa

**Sent:** Tuesday, December 18, 2018 11:55 AM

**To:** Jones, Russell <[Jones.Russell@epa.gov](mailto:Jones.Russell@epa.gov)>; McNally, Robert <[McNally.Robert@epa.gov](mailto:McNally.Robert@epa.gov)>; Varco, Joseph <[varco.joseph@epa.gov](mailto:varco.joseph@epa.gov)>; Ambrosino, Helene <[Ambrosino.Helene@epa.gov](mailto:Ambrosino.Helene@epa.gov)>; Gsell, Alyssa <[Gsell.Alyssa@epa.gov](mailto:Gsell.Alyssa@epa.gov)>; VanAkkeren, Brett <[VanAkkeren.Brett@epa.gov](mailto:VanAkkeren.Brett@epa.gov)>; Wyatt, TJ <[Wyatt.TJ@epa.gov](mailto:Wyatt.TJ@epa.gov)>; Hofmann, Angela <[Hofmann.Angela@epa.gov](mailto:Hofmann.Angela@epa.gov)>; Chumble, Prasad <[Chumble.Prasad@epa.gov](mailto:Chumble.Prasad@epa.gov)>; Smoot, Cameo <[Smoot.Cameo@epa.gov](mailto:Smoot.Cameo@epa.gov)>; Watkins, Stephen <[watkins.stephen@epa.gov](mailto:watkins.stephen@epa.gov)>; Hoyt, Sarita <[Hoyt.Sarita@epa.gov](mailto:Hoyt.Sarita@epa.gov)>; Mosby, Jackie <[Mosby.Jackie@epa.gov](mailto:Mosby.Jackie@epa.gov)>; Miller, Wynne <[Miller.Wynne@epa.gov](mailto:Miller.Wynne@epa.gov)>

**Subject:** FW: FROM OMB: EO 12866 Interagency Review: EPA's Guidance for Plant Biostimulant Products: Label Claims Excluded or Regulated under FIFRA as Plant Regulator Claims (RIN 2070-ZA21) - Interagency Comments

Hi all,

I talked with Danielle about the biostimulants guidance during our bi-weekly meeting this morning.

She mentioned that USDA had comments on the guidance document that they will send to her today. Danielle will get them to us as soon as she can.

## Ex. 5 Deliberative Process (DP)

Please note that the call with DOJ will need to be scheduled the 1<sup>st</sup> week of January. DOJ indicated that they are available on January 3<sup>rd</sup>, 7<sup>th</sup> and 8<sup>th</sup>. Please let me know your availability (2 or more times if possible).

I'm attaching a revised version of the FR Notice.

Thanks!

-Melissa

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**From:** Gsell, Alyssa

**Sent:** Monday, December 17, 2018 4:04 PM

**To:** Chun, Melissa <[Chun.Melissa@epa.gov](mailto:Chun.Melissa@epa.gov)>; Jones, Russell <[Jones.Russell@epa.gov](mailto:Jones.Russell@epa.gov)>; McNally, Robert <[McNally.Robert@epa.gov](mailto:McNally.Robert@epa.gov)>; Varco, Joseph <[varco.joseph@epa.gov](mailto:varco.joseph@epa.gov)>; Ambrosino, Helene <[Ambrosino.Helene@epa.gov](mailto:Ambrosino.Helene@epa.gov)>; VanAkkeren, Brett <[VanAkkeren.Brett@epa.gov](mailto:VanAkkeren.Brett@epa.gov)>; Wyatt, TJ <[Wyatt.TJ@epa.gov](mailto:Wyatt.TJ@epa.gov)>; Hofmann, Angela <[Hofmann.Angela@epa.gov](mailto:Hofmann.Angela@epa.gov)>; Chumble, Prasad <[Chumble.Prasad@epa.gov](mailto:Chumble.Prasad@epa.gov)>; Smoot, Cameo <[Smoot.Cameo@epa.gov](mailto:Smoot.Cameo@epa.gov)>; Watkins, Stephen <[watkins.stephen@epa.gov](mailto:watkins.stephen@epa.gov)>; Hoyt, Sarita <[Hoyt.Sarita@epa.gov](mailto:Hoyt.Sarita@epa.gov)>; Mosby, Jackie <[Mosby.Jackie@epa.gov](mailto:Mosby.Jackie@epa.gov)>

**Subject:** RE: FROM OMB: EO 12866 Interagency Review: EPA's Guidance for Plant Biostimulant Products:

## Ex. 5 Deliberative Process (DP)

Thanks.

Alyssa M. Gsell  
US EPA Office of General Counsel  
Phone: 202-564-7413  
Fax: 202-564-5416

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**From:** Chun, Melissa

**Sent:** Sunday, December 16, 2018 6:49 PM

**To:** Jones, Russell <[Jones.Russell@epa.gov](mailto:Jones.Russell@epa.gov)>; McNally, Robert <[McNally.Robert@epa.gov](mailto:McNally.Robert@epa.gov)>; Varco, Joseph <[varco.joseph@epa.gov](mailto:varco.joseph@epa.gov)>; Ambrosino, Helene <[Ambrosino.Helene@epa.gov](mailto:Ambrosino.Helene@epa.gov)>; Gsell, Alyssa <[Gsell.Alyssa@epa.gov](mailto:Gsell.Alyssa@epa.gov)>; VanAkkeren, Brett <[VanAkkeren.Brett@epa.gov](mailto:VanAkkeren.Brett@epa.gov)>; Wyatt, TJ <[Wyatt.TJ@epa.gov](mailto:Wyatt.TJ@epa.gov)>; Hofmann, Angela <[Hofmann.Angela@epa.gov](mailto:Hofmann.Angela@epa.gov)>; Chumble, Prasad <[Chumble.Prasad@epa.gov](mailto:Chumble.Prasad@epa.gov)>; Smoot, Cameo <[Smoot.Cameo@epa.gov](mailto:Smoot.Cameo@epa.gov)>; Watkins, Stephen <[watkins.stephen@epa.gov](mailto:watkins.stephen@epa.gov)>; Hoyt, Sarita <[Hoyt.Sarita@epa.gov](mailto:Hoyt.Sarita@epa.gov)>; Mosby, Jackie <[Mosby.Jackie@epa.gov](mailto:Mosby.Jackie@epa.gov)>

**Subject:** FW: FROM OMB: EO 12866 Interagency Review: EPA's Guidance for Plant Biostimulant Products: Label Claims Excluded or Regulated under FIFRA as Plant Regulator Claims (RIN 2070-ZA21) - Interagency Comments

Hi all,

Here's the mark-up for the FR Notice.

## Ex. 5 Deliberative Process (DP)

Please forward your comments to everyone on this e-mail.

Thanks!

-Melissa

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**From:** Chun, Melissa

**Sent:** Friday, December 14, 2018 12:08 PM

**To:** Jones, Russell <[Jones.Russell@epa.gov](mailto:Jones.Russell@epa.gov)>; McNally, Robert <[McNally.Robert@epa.gov](mailto:McNally.Robert@epa.gov)>; Varco, Joseph <[varco.joseph@epa.gov](mailto:varco.joseph@epa.gov)>; Ambrosino, Helene <[Ambrosino.Helene@epa.gov](mailto:Ambrosino.Helene@epa.gov)>; Gsell, Alyssa <[Gsell.Alyssa@epa.gov](mailto:Gsell.Alyssa@epa.gov)>; VanAkkeren, Brett <[VanAkkeren.Brett@epa.gov](mailto:VanAkkeren.Brett@epa.gov)>; Hofmann, Angela <[Hofmann.Angela@epa.gov](mailto:Hofmann.Angela@epa.gov)>; Chumble, Prasad <[Chumble.Prasad@epa.gov](mailto:Chumble.Prasad@epa.gov)>; Smoot, Cameo

<Smoot.Cameo@epa.gov>; Watkins, Stephen <watkins.stephen@epa.gov>; Hoyt, Sarita <Hoyt.Sarita@epa.gov>; Mosby, Jackie <Mosby.Jackie@epa.gov>

**Subject:** FW: FROM OMB: EO 12866 Interagency Review: EPA's Guidance for Plant Biostimulant Products: Label Claims Excluded or Regulated under FIFRA as Plant Regulator Claims (RIN 2070-ZA21) - Interagency Comments

We walked through the comments, made assignments, and flagged one that will need to be raised to the DAA's.

## Ex. 5 Deliberative Process (DP)

We'll send the mark-ups around on Monday for folks to comment on.

This is the comment that was flagged in the Summary for the guidance document:

## Ex. 5 Deliberative Process (DP)

After we've agreed on the responses/edits, the documents will go to Rick and the DAA's on Tuesday for their approval, before sending the responses to OMB.

Please note that there might be a second set of comments from USDA next Tuesday.

Thanks everyone!

-Melissa

**Melissa L Chun** | US EPA | Regulatory and Information Coordination Staff | Office of Chemical Safety and Pollution Prevention | 1200 Pennsylvania Ave., NW | William Jefferson Clinton Building East Room 3425E, Mail Code 7101M | Washington DC 20460 | phone: (202) 564-1605

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**From:** Chun, Melissa

**Sent:** Friday, December 14, 2018 9:35 AM

**To:** Jones, Russell <Jones.Russell@epa.gov>; McNally, Robert <McNally.Robert@epa.gov>; Varco, Joseph <varco.joseph@epa.gov>; Ambrosino, Helene <Ambrosino.Helene@epa.gov>; Gsell, Alyssa <Gsell.Alyssa@epa.gov>; VanAkkeren, Brett <VanAkkeren.Brett@epa.gov>; Hofmann, Angela <Hofmann.Angela@epa.gov>; Chumble, Prasad <Chumble.Prasad@epa.gov>; Smoot, Cameo <Smoot.Cameo@epa.gov>; Watkins, Stephen <watkins.stephen@epa.gov>; Hoyt, Sarita <Hoyt.Sarita@epa.gov>

**Subject:** FROM OMB: EO 12866 Interagency Review: EPA's Guidance for Plant Biostimulant Products: Label Claims Excluded or Regulated under FIFRA as Plant Regulator Claims (RIN 2070-ZA21) - Interagency Comments

Hi all,

Here are the interagency reviewer comments from OMB.

We go through them at 11 am.

-Melissa

**Melissa L Chun** | US EPA | Regulatory and Information Coordination Staff | Office of Chemical Safety and Pollution Prevention | 1200 Pennsylvania Ave., NW | William Jefferson Clinton Building East Room 3425E, Mail Code 7101M | Washington DC 20460 | phone: (202) 564-1605

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**From:** Jones, Danielle Y. EOP/OMB <[Danielle\\_Y\\_Jones@omb.eop.gov](mailto:Danielle_Y_Jones@omb.eop.gov)>  
**Sent:** Friday, December 14, 2018 9:29 AM  
**To:** Chun, Melissa <[Chun.Melissa@epa.gov](mailto:Chun.Melissa@epa.gov)>  
**Cc:** Hofmann, Angela <[Hofmann.Angela@epa.gov](mailto:Hofmann.Angela@epa.gov)>; VanAkkeren, Brett <[VanAkkeren.Brett@epa.gov](mailto:VanAkkeren.Brett@epa.gov)>  
**Subject:** EO 12866 Interagency Review: EPA's Guidance for Plant Biostimulant Products: Label Claims Excluded or Regulated under FIFRA as Plant Regulator Claims (RIN 2070-ZA21)

Good morning Melissa,

Please find attached the interagency reviewers comments on the Guidance for Plant Biostimulant Products: Label Claims Excluded or Regulated under FIFRA as Plant Regulator Claims (RIN 2070-ZA21).

Please let me know if you have any questions.

Best,  
Danielle

Danielle Y. Jones  
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Office of Management and Budget  
Phone: (202) 395-1741 | [djones@omb.eop.gov](mailto:djones@omb.eop.gov)